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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER

ART UNIT	PAPER NUMBER
1644	11

DATE MAILED: 05/23/01

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 8/31/99; 3/5/01

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 44-55 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) 44-55 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

☆ U.S. GPO: 1996-421-632/40206

DETAILED ACTION

1. Applicant's amendment, filed 3/5/01 (Paper No. 8), is acknowledged.
Applicant's second preliminary amendment, filed 8/31/99 originally, has been entered.
Claims 1 has been canceled. Claims 2-43 have been canceled previously.
Claims 44-55 have been added.

2. Applicant should amend the first line of the specification to cross reference related applications and update the status of priority documents.
For example, USSN 08/475,873 is now U.S. Patent No. 5,942,229.
And the proper designation of the earliest priority document is USSN 08/115,990 (not 08/111,990).
Also, applicant should indicate priority to PCT/US94/09872 indicated in the oath/declaration.

3. Formal drawings have been submitted which comply with 37 CFR 1.84.

4. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

Trademarks should be capitalized or accompanied by the ™ or ® symbol wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the trademarks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

5. The following is a quotation of the first paragraph of 35 U.S.C. § 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 44-55 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. The specification as originally filed does not provide support for the invention as now claimed: "wherein prolonged humoral immune that antibody production remains suppressed after the anti-gp39 has been cleared from the subject"

Applicant's amendment, filed 3/5/01 (Paper No. 8), including the submission of applicant's second preliminary amendment, filed 8/31/99 originally, does not provide sufficient direction for the written description for the above-mentioned "limitation".

The specification as filed does not provide a sufficient written description for this phrase. The specification does not provide blazemarks nor direction for the instant methods encompassing the above-mentioned "limitations" as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the "limitations" indicated above. See MPEP 714.02 and 2163.06

7. Claims 44-55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 44-55 are indefinite in the recitation of "TD" because this term should be spelled out to clearly define their meaning, at least upon first time usage.

B) Claims 44-55 are indefinite in the recitation "wherein prolonged humoral immune that antibody production remains suppressed after the anti-gp39 has been cleared from the subject" because the claims recite antagonists other than "anti-gp39 antibodies". Therefore, it is not clear whether this "limitation" refers to the use of "anti-gp39 antibodies in the claimed methods or that it was intended that the other antagonists were to be included in this "limitation".

C) Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

8. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 44-49 and 51-53 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobbold et al. (U.S. Patent No. 6,056,956) in view of Lederman et al. (U.S. Patent No. 5,474,771; 1449, #AA) OR Armitage et al. (U.S. Patent No. 6,087,329).

Cobbold et al. teach the use of CD4-specific antibodies to induce specific non-responsiveness or tolerance to various molecules, including globular proteins, glycoproteins and polypeptides intended for therapeutic use and allergens (see entire document; including column 2, paragraph 4; column 3, paragraphs 5-6).

Cobbold et al. differ from the claimed methods by not teaching the preferred embodiments of targeting the CD40L/gp39 with CD40L-specific antibodies.

Lederman et al. teach inhibiting various immune responses with 5C8-specific antibodies (see entire document, including columns 6-7, 11); including allergies (column 11, paragraph 6). The 5C8 specificity is the equivalent of human CD40L.

Armitage et al. teach inhibiting various immune responses with CD40 antagonists, including soluble CD40, CD40Ig, monomeric CD40L (e.g. columns 10-11, including overlapping paragraph, columns 14-17; column 21); inlcuding targeting allergies, including IL-4 induced IgE responses (e.g. column 10, paragraph 3 - column 11, paragraph 1; column 15, paragraph 1-2; Examples 8-11, 13).

Given the ability of 5C8-/CD40L-specific antibodies, as taught by Lederman et al. OR the ability of various CD40 antagonists, as taught by Armitage et al. to inhibit various immune responses, including T helper cell-mediated immune responses, including humoral responses; one of ordinary skill in the art at the time the invention was made would have been motivated to substitute these antagonists into the methods of Cobbold et al. to similarly target T helper cells to inhibit humoral responses to thymus-dependent antigens. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

10. Claims 50, 54, 55 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cobbold et al. (U.S. Patent No. 6,056,956) in view of Lederman et al. (U.S. Patent No. 5,474,771; 1449, #AA) OR Armitage et al. (U.S. Patent No. 6,087,329).
As applied to claims 44- 49, 51-53 above
and in further view of Ramanathan et al. (WO 91/09059).

Cobbold et al., Lederman et al. and Armitage et al. are taught above and differ from the claimed methods by not disclosing the use of IL-4-specific antibodies.

Ramanathan et al. Teach the use of IL-4-specific antagonists such as IL-4-specific antibodies to inhibit or treat allergic responses (see entire document, including page 1, paragraph 3; Summary of the Invention; Description f the Invention, page 6, paragraph 2, pages 13-16).

Combination therapy was known and practiced at the time the invention was made.
It is prima facie obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art. In re Kerkhoven, 205 USPQ 1069, CCPA 1980. See MPEP 2144
Given the prior art teachings of using both CD40:CD40L-specific inhibitors and IL-4-specific inhibitors to inhibit allergic responses; the ordinary artisan would have been motivated to combine both said inhibitors to down regulate responses to allergens at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

11. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and © may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 44-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,942,229.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims anticipate the instant method claims.

In addition, when the instant claims are read in light of the specification; the patented claims are the preferred embodiments and again anticipate the instant claims.

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, Ph.D.
Primary Examiner
Technology Center 1600
May 21, 2001

John J. Doll, Director
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